REMARKS

In response to the final Office Action mailed September 7, 2001, the present application has been carefully reviewed and amended. Entry of the present amendments and reconsideration of the application is respectfully requested.

Claim Objections

Claims 34 and 35

Claims 34 and 35 have been amended to terminate with "curve.".

Rejections Under 35 U.S.C. §112

Claim 22

Claim 22 stands rejected under 35 U.S.C. §112, second paragraph, for the recitation of "the corrective produce." Claim 22 has been amended to recite "the corrective procedure."

Allowable Subject Matter

Claims 8, 21, 34 and 35 have been deemed to include allowable subject matter. Claims 34 and 35 have been amended to address the outstanding claim objections. Claims 8 and 21 have been cancelled.

The remaining claims in the application have been amended to recite, in part, "the correspondence relates blood flow to $= \frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve" (Claims 2-6, 30, 31, 34 and 36); "the signal corresponding to a relationship of flow rate $= \frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve" (Claims 9-14, 32, 33, 35 and 37); "the controller selected to calculate the blood flow corresponding to $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve" (Claims 15 and 38); "and $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and

$\int C(t)dt$ is an area under a dilution curve" (Claims 16-18, 39 and 40); "and $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve" (Claims 19 and 41); "provide a signal for determining a blood flow corresponding to $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve" (Claims 22-24); "the determined blood flow corresponding to $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve" (Claims 25-29 and 42).

Therefore, these Claims are also believed to be in condition for allowance.

Claims 36 - 42

Newly added dependent Claims 36 - 42 include subject matter disclosed in Figures 7, 15 and 16; pages 16, 17 and 20.

Information Disclosure Statement

Applicant request confirmation of the Information Disclosure Statement mailed January 26, 2001, a copy of which is attached.

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Therefore, applicant respectfully submits all the pending claims, Claims 2-6, 9-19 and 22-42 are in condition for allowance and such action is earnestly solicited. If, however, Examiner Szmal feels that any further issues remain, he is cordially invited to call the undersigned so that such matters can be promptly resolved.

Respectfully submitted,

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VERSION WITH MARKINGS SHOWING CHANGES

In the Specification:

Please amend the paragraph spanning page 16, line 17 to page 17, line 2, as follows:

For example, in measuring hemodialysis vascular access flow, the controller 60 measures the access flow by monitoring the passage of completely mixed indicator in the blood. Referring to Figure 7, the concentration curve resulting from the introduction and mixing of the indicator is recorded by the sensor. Access flow, AF, is then calculated according to:

$$AF = \frac{V}{\int C(t)dt}$$

where V is the volume of indicator introduced, $\int C(t)dt$ is the area under the dilution curve that is equal to the average concentration of the indicator in the flow for the duration of the curve multiplied by the duration of the dilution [duration of the] curve.

In the Claims:

Please cancel claim 1. An apparatus for determining a blood flow in a vessel, comprising:

(a) an elongate catheter having a stenosis reducing member, a blood property change port located to alter a blood property outside the catheter and a downstream sensor spaced from the port for producing a signal corresponding to the [blood property in] blood flow between the catheter and the vessel.

2. (Once Amended) The apparatus of Claim 34 [1], wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects.

3. (Once Amended) The apparatus of Claim 34 [1], further comprising a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor.

4. (Once Amended) The apparatus of Claim 34 [1], wherein the blood property change port includes an aperture for introducing a blood property variant.

5. (Once Amended) The apparatus of Claim 34 [1], wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow.

6. (Once Amended) The apparatus of Claim 34 [1], wherein the blood property change port includes one of a heat sink and a heat source for creating a local temperature gradient.

Please cancel claim 7. The apparatus of Claim 1, wherein the signal from the sensor corresponds to a blood flow in the vessel.

Please cancel claim 8. The apparatus of Claim 7, wherein the correspondence relates blood flow to $= \frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

9. (Twice Amended) A stenosis reducing catheter, comprising:

(a) a stenosis reducing member selectively actuatable to reduce stenosis in a vessel;

(b) a port for inducing a blood property change to blood flowing external to the stenosis reducing catheter; and

(c) a sensor spaced from the blood property change port for providing a signal corresponding to a change in a blood property external to the stenosis reducing catheter, the signal corresponding to a relationship of flow rate = $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

10. The catheter of Claim 9, wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects.

11. (Once Amended) The catheter of Claim 9, further comprising a controller operably connected to the sensor to calculate [a] the flow rate corresponding to the signal from the downstream sensor.

12. The catheter of Claim 9, wherein the port includes an aperture for introducing a blood property variant.

13. The catheter of Claim 9, wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow.

14. The catheter of Claim 9, wherein the port includes one of a heat sink and a heat source for creating a local temperature gradient.

15. (Thrice Amended) An apparatus for determining blood flow, comprising:

(a) a dilution indicator source;

(b) a catheter connectable to the dilution indicator source, the catheter having means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough to pass from the catheter and a downstream sensor for producing a signal corresponding to passage of the dilution indicator external to the catheter; and

(c) a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor, the controller selected to calculate the blood flow corresponding to $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

16. (Thrice Amended) A method for quantitatively measuring a reduced stenosis induced flow change, comprising:

(a) inserting a catheter and a blood property sensor into a vessel having a blood flow corresponding to the stenosis;

(b) introducing a first change in a blood property in a blood flow outside the catheter and upstream of the blood property sensor;

(c) detecting passage of the first change in the blood property at the blood property sensor;

(d) reducing the stenosis of in the vessel;

(e) introducing a second change in the blood property upstream of the sensor;

(f) detecting passage of the second change in the blood property at the blood property sensor; and

(g) determining a change in blood flow corresponding to (i) the detected passage of the first change in the blood property; (ii) [and] the second change in the blood property; and $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

17. The method of Claim 16, wherein inserting a catheter and a blood property sensor into a vessel includes inserting a first catheter having a stenosis reducing member and a second catheter having the blood property sensor.

18. The method of Claim 16, wherein inserting a catheter and a blood property sensor into a vessel includes inserting a catheter having a stenosis reducing member and the blood property sensor.

19. (Thrice Amended) A method of monitoring blood flow during a vascular corrective procedure, comprising:

(a) inserting a catheter into a vessel;

(b) employing the catheter to perform a vascular correction in the vessel;

(c) introducing a first blood property change into a blood flow outside the catheter;

(d) detecting passage of the first blood property change past a downstream sensor on the catheter; and

(e) calculating the blood flow in response to the change in blood property and passage of the blood property past the downstream sensor, and $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

Please cancel 20. An apparatus for determining blood flow in a vascular passage, comprising:

(a) a catheter having means for increasing the effective size of a portion of the vascular passage, the catheter including a dilution indicator introduction

port located to pass a dilution indicator from the catheter and a downstream blood property sensor; and

(b) a controller operably connected to the blood property sensor for calculating a flow through the vascular passage corresponding to a signal from the blood property sensor.

Please cancel claim 21. The apparatus of Claim 20, wherein the controller determines the flow corresponding to the relation $AF = \frac{V}{\int C(t)dt}$ where AF corresponds to the flow, V is a volume of indicator introduced and $\int C(t)dt$ is the area under a dilution curve.

22. (Twice Amended) An apparatus for determining an intra-procedural blood flow in a corrective procedure, comprising:

(a) a catheter;

(b) a blood parameter altering section on the catheter located to alter a blood parameter external to the catheter;

(c) means for effecting the corrective <u>procedure</u> [produce]; and

(d) a blood parameter sensor connected to the catheter and spaced from the blood parameter altering section to sense the altered blood parameter external to the catheter <u>and provide a signal for determining a blood flow corresponding to</u> $\underline{\frac{V}{\int C(t)dt}}$ <u>where V is the volume of indicator introduced and</u> $\underline{\int C(t)dt}$ <u>is an area under a dilution curve</u>.

23. The apparatus of Claim 22, wherein the blood altering section includes one of a port and a temperature gradient generator.

24. The apparatus of Claim 22, further comprising a controller connectable to the altering section and the blood parameter sensor to calculate the blood flow.

25. (Twice Amended) A method of monitoring a stenosis reducing procedure in a vessel, comprising:

(a) locating a blood parameter altering section in the vessel to alter a blood parameter in a blood flow contacting the vessel;

(b) locating a blood parameter sensor downstream of the altering section;

(c) performing the stenosis reducing procedure; and

(d) determining a blood flow in response to a passage of an altered blood property past the blood parameter sensor, the determined blood flow corresponding to $\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

26. The method of Claim 25, wherein performing the stenosis reducing procedure includes angioplasty.

27. The method of Claim 25, further comprising locating the blood parameter sensor to reduce wall effects from the vessel.

28. The method of Claim 25, further comprising rotating the blood parameter sensor with respect to the vessel to reduce wall effects from the vessel.

29. The method of Claim 25, further comprising locating a plurality of blood parameter sensors in the vessel.

30. (Once Amended) The apparatus of Claim 34 [1], wherein the sensor detects changes in one of electrical impedance and electrical resistance.

31. (Once Amended) The apparatus of Claim 34 [1], wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

32. The catheter of Claim 35 [9], wherein the sensor detects changes in one of electrical impedance and electrical resistance.

33. The catheter of Claim 35 [9], wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

34. (Once Amended) An apparatus for determining a blood flow in a vessel, comprising:

(a) an elongate catheter having a stenosis reducing member, a blood property change port located to alter a blood property outside the catheter and a downstream sensor spaced from the port for producing a signal corresponding to

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the blood property in a blood flow in the vessel, and the correspondence relates blood flow to $= \frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.[.]

35. (Once Amended) An apparatus for determining blood flow in a vascular passage, comprising:

(a) a catheter having means for increasing the effective size of a portion of the vascular passage, the catheter including a dilution indicator introduction port and a downstream blood property sensor; and

(b) a controller operably connected to the blood property sensor for calculating a blood flow through the vascular passage corresponding to a signal from the blood property sensor and corresponding to the relation $AF = \frac{V}{\int C(t)dt}$ where AF corresponds to the blood flow, V is a volume of indicator introduced and $\int C(t)dt$ is the area under a dilution curve[.].

36. (New) The apparatus of Claim 34, wherein the volume of indicator introduced is one of a bolus and a constant infusion.

37. (New) The apparatus of Claim 35, wherein the volume of indicator introduced is one of a bolus and a constant infusion.

38. (New) The apparatus of Claim 15, wherein the dilution indicator source is selected to introduce one of a bolus injection and a constant infusion.

39. (New) The method of Claim 16, wherein introducing the first change in the blood property includes introducing one of a bolus injection and a constant infusion.

40. (New) The method of Claim 16, wherein introducing the second change in the blood property includes introducing one of a bolus injection and a constant infusion.

41. (New) The method of Claim 19, wherein introducing the first blood property change includes introducing one of a bolus injection and a constant infusion.

42. (New) The method of Claim 25, further comprising altering the blood property by introducing one of a bolus injection and a constant infusion.

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